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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,030

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Stephen George Edward Barker

117-554 (AMK)

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NIXON & VANDERHYE, PC

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EXAMINER

ANDERSON, GREGORY A

ART UNIT

PAPER NUMBER

3773

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/542,030

Applicant(s)BARKER, STEPHEN GEORGE
EDWARD**Examiner**

GREGORY A. ANDERSON

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-41 is/are pending in the application.
- 4a) Of the above claim(s) 36-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-35 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09272005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 8 April 2008 is acknowledged. The traversal is on the ground(s) that the two separate inventions are close enough in subject matter that there would be no burden on the examiner to search both groups. This is not found persuasive because the claims of the nonelected group do not require the particulars of the elected group and are directed to a separate and distinct invention.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 36-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8 April 2008.

Claim Objections

3. Claims 24, 26, 28-34 are objected to because of the following informalities: the phrase "sheet of surgical material" in claim 23 is changed multiple times throughout the above listed claims to "the sheet" and "the sheet material". In the interests of clarity, all instances of "the sheet" and "the sheet material" should be changed to --the sheet of surgical material--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 26, 27, 29, 34, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 26: it is unclear whether applicant is claiming the sheet material or a combination thereof.

Regarding claim 27: the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 29: A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 29 recites the broad recitation "flat flexible sheet", and the claim also recites "preferably circular" which is the narrower statement of the range/limitation.

Regarding claim 34: It is unclear whether applicant is claiming the sheet or a combination thereof.

6. Regarding claim 39: Claim 39 recites the limitation "said laparoscopic port" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 23-35, 39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Himpens et al. 5,397,331.

Regarding claim 23: Himpens et al. discloses an applicator assembly comprising; a deployment sleeve 23; a plunger 20; a sheet of surgical material 13 which can be folded, or collapsed; and an actuating means 14 operative to unfold or erect the sheet following expulsion from the distal end of the deployment sleeve through longitudinal movement of the plunger; wherein the deployment sleeve is provided with an external flange to control the length of insertion of the deployment sleeve in the port (Fig. 10).

Regarding claim 24: Himpens et al. further disclose a pulling means 19 operative to apply a pull force to the sheet following deployment.

Regarding claim 25: Himpens et al. further discloses the pulling means being a suture 19.

Regarding claim 26: Himpens et al. further discloses the sheet material, in use, is encased and protected within the deployment sleeve during the manipulation procedure to position the sleeve at the termination of the opening after which the sheet is expelled by the plunger to be erected to close behind and over the internal area of the opening (Figs. 6-9).

Regarding claim 27: Himpens et al. further discloses the sheet of surgical material comprises a known surgically compatible mesh such as polypropylene, preferably including a PTFE or similar non-stick material on one surface, being the innermost facing surface adjacent the applicator (Col. 5 ll. 2-4).

Regarding claim 28: Himpens et al. further discloses the entire sheet is wholly of PTFE (Col. 5 ll. 2-4).

Regarding claim 29: Himpens et al. further discloses the sheet material being normally a flat flexible sheet, preferably circular, and includes radial ribs 14 forming more rigid but resilient arms through which, when the sheet is forced to a collapsed or folded configuration, the sheet is caused to open out to restore the flat form (Col. 5 ll. 2-4, Fig. 3).

Regarding claim 30: Himpens et al. further discloses the opening being affected through the properties of the sheet material itself (Col. 5 ll. 4-13).

Regarding claim 31: Himpens et al. further discloses the opening being effected or assisted through a suture which pulls the sheet upward towards the applicator (Figs. 6-9).

Regarding claim 32 Himpens et al. further discloses the sheet including ribs 14 which have preformed fold creases to facilitate collapse to a predetermined configuration.

Regarding claim 33: Himpens et al. further discloses the sheet including ribs 14 which have a "memory" acting to restore the sheet to a flat form.

Regarding claim 34: (Himpens et al. further discloses, in use, after deployment of the sheet the opening thereof is effected or assisted by a separate actuating means which may comprise a suture needle, with or without an attached suture, extending through the plunger from the proximal to the distal end of the sleeve and connecting with the sheet, the suture being arranged so that a pulling force applied thereto opens the sheet (Figs. 8-9).

Regarding claim 35: Himpens et al. further discloses the plunger being provided with a flange to control the position of the plunger in the Sleeve (Fig. 12).

Regarding claim 39: Himpens et al. discloses a combination, of the applicator assembly of claim 23 and a laparoscopic port, wherein the deployment sleeve of the applicator assembly is appropriately dimensioned to pass down the port (Col. 1ll. 41-43, Figs. 6-9).

Regarding claim 41: Himpens et al. further discloses instruments for use in the laparoscopic surgery 12, 13, 23.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Himpens et al. in view of optimization of ranges.

Himpens et al. discloses the invention as discussed in claim 39 above.

However, Himpens et al. does not disclose the laparoscopic port having a nominal diameter of 5 to 10 mm.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Himpens et al. to find the nominal workable range since it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY A. ANDERSON whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30am-3:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory A Anderson/

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773